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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,400	12/20/2001	Diana Zanini	VTN-568	3607

27777 7590 08/28/2003

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/28/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/028,400

Applicant(s)

ZANINI ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6/11/2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 25-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 18-24 is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION*****Election/Restrictions***

Applicant's election of Group I, claims 1-54 and monomer CYST in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

During a telephone conversation with Karen Harding on 3/7/2003, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-54 and a monomer of Formula I, N,N'-(bisacryloyl)cystamine (CYST). Affirmation of this election must be made by applicant in replying to this Office action. During the course of prosecution of the elected species in relation to the elected Group I, it appears that an antimicrobial contact lens comprising silver and a polymer comprising the CYST monomer may be allowable. As such, the elected species was expanded to include all of Formula I. As such, Claims 25-72 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Objections***

Claims 18-24 are objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Examiner notes that Applicant may satisfy the requirement of including all of the limitations of the base claim without having to repeat the entire listing of all of the monomers of Formulas I-IV. For example "An antimicrobial lens comprising silver and a polymer comprising the monomer [insert the formula of CYST], wherein the lens is a silicone

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hydrogel. Alternatively, if Applicant wishes to retain the "Formula I" language, Applicant could set out Formula I and the specific definitions of the variables which would define the monomer CYST.

### *Specification*

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-9, 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 05-269181.

JP 05-3269181 expressly discloses an antimicrobial soft contact lens comprising 69.7 w% 2-hydroxyethyl methacrylate, 24.6 w% methyl methacrylate, 0.4 w% ethylene glycol dimethacrylate and 5w% silver acrylacetate or 5w% silver benzoyl acetate (paragraphs 0052-0055). The rejection is based on an interpretation of the limitation "about" to include amounts greater than the specifically set forth range, including amount expressly disclosed in the prior art.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that 2-propanone is not included in the Markush group for R2 or R2 and R3 taken together. However, the claims do not require that the monomer and silver must be a single compound. The claims only require that there be a monomer of formula I and silver. Applicant has not addressed the other monomers in the rejection, as such, the rejection is maintained.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over by JP 05-269181 in view of the acknowledged prior art, Vanderlaan et al. (US Pat. 5,998,498), Laskey (US Pat. 3,929,741).

JP 05-3269181 teaches an antimicrobial soft contact lens comprising an antimicrobial substance, such as an acrylacetate or benzoyl acetate complex of silver, ranging from 0.1 to 20% by weight, polymers of monomers, including methacrylic and acrylic esters, siloxanyl alkyl (meta) acrylate, carboxylic acid vinyls, acrylic acid, methacrylic acid, methyl methacrylate, hydroxyethyl methacrylate, dimethyl acrylamide, glycol acrylates and glycol methacrylates (paragraphs 0009-0012, 0024-0027). Specific examples of soft contact lenses are taught containing 69.7 w% 2-hydroxyethyl methacrylate, 24.6 w% methyl methacrylate, 0.4 w% ethylene glycol dimethacrylate and 5w% silver acrylacetate or 5w% silver benzoyl acetate (paragraphs 0052-0055). It is taught that the amount of the antibacterial substance to be added depends on the maintenance of transparency and antimicrobial activity (paragraph 0028).

Applicant acknowledges that soft contact lenses based on hydrogels are widely used because they are more comfortable but that extended use encourages the build of bacteria and other microbes (Pg. 1). It is acknowledged that examples of these soft contact lens, include

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etafilcon A, balafilcon A, aquafilcon A, lenefilcon, lotrafilcon and silicone hydrogels (Pg. 20, lines 1-8).

Vanderlaan et al. teach that soft contacts can be prepared from silicone hydrogels which combine silicone containing monomers and hydrophilic monomers (See entire reference, especially column 5).

Laskey teaches that hydrophilic monomers of acrylamido sulfonic acid or sulfonate are suitable for soft contact lenses and have greater water retention and because of a greater ability for cross-linking have increased flexibility in the modification of physical properties (Column 1).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an antimicrobial contact lens comprising silver and a polymer comprising a monomer of formula I in which R3 being substitute phenyl, the claimed organic sulfonic acid, organic phosphoric acid or organic disulfide, or the lens is etafilcon A, balafilcon A, aquafilcon A, lenefilcon, lotrafilcon or silicone hydrogel. However, the prior art amply suggests the same as antimicrobial soft contact lenses containing silver and monomers falling with the scope of formula I are known in the art. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties and, thus, avoid the problems associated with extended wear.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above.

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Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

**Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

August 25, 2003

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1616